

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :  
SHIMIZU et al. :  
Serial No. 09/403,429 : Group Art Unit 1615  
Filed on October 20, 1999 : Examiner TRAN,S  
For RAPIDLY DISINTEGRABLE SOLID PREPARATION

## DECLARATION UNDER 37 CFR §1.132

Honorable Commissioner of Patent and Trademarks, Washington, D.C.

Sir,

I, Jun-ichi WATANABE declare:

That I am a citizen of Japan residing at 1-2-10-1407, Kami-cho,  
Ageo-shi (Ageo City), Saitama Prefecture, Japan;

That I was born on February 24, 1948 in Niigata Prefecture, Japan;

That I graduated from Nagaoka Industrial High Occupational School,  
Applied Chemistry Course in March of 1968;

That I have been employed by ShinEtsu Chemical Co., Ltd. since April  
of 1968 and was engaged in the research and development of  
polyvinylchloride until 1989;

That I have been engaged in marketing and sale of celluloses in  
Cellulose Department of said Company;

That I have been appointed Head of said Cellulose Department in said  
Company since July of 2001;

That prior to July 28, 1998, ShinEtsu had not commercially supplied  
L-HPC having a hydroxypropoxyl content in the range of 5-7%;

That prior to July 28, 1998, ShinEtsu had supplied only L-HPC having  
the following ranges of hydroxypropoxyl content:

7.0 – 9.9% as LH-22 or LH-32

10.0 – 12.9% as LH-21 or LH-31 and

13.0 – 16.0% as LH-20 or LH-30;

It is declared by the undersigned that all statements made herein of his knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 6 day of December , 2001.

  
Jun-ichi WATANABE



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## DECLARATION UNDER 37 CFR §1.132

Honorable Commissioner of Patent and Trademarks,  
Washington, D.C.

Sir,

I, Yasuo Ohno, declare:

That I am a citizen of Japan residing at 3-4-15-410, Tagawa,  
Yodogawa-ku, Osaka, Japan;

That I was born on December 3, 1950 in Yamaguchi Prefecture, Japan;

That I graduated from Fukui Prefectural Takefu Engineering High  
School in March 10, 1969 ;

That I have been employed by Takeda Chemical in 1969 and was  
engaged in chemical synthesis and research and development of  
pharmaceutical formulations;

That I have been engaged in research and development in the Health  
Care Research Laboratories of Consumer Healthcare Internal Company of  
said company since 1997 ;

That I have been appointed Assistant Research Head of in said  
Company;

That I am a co-inventor of U.S. Patent No. 5,958,453, entitled "Solid  
Pharmaceutical Preparation with Improved Buccal Disintegrability and/or  
Dissolubility";

That I have read and understood U.S. Patent Application Serial No.  
09/403,429, and the Office Action dated October 2, 2001;

That the hydroxypropylcellulose content of the low substituted  
hydroxycellulose (L-HPC) utilized in Comparative Examples 3, 4 and 5 was

10.0 % by weight or more to less than 12.9% by weight of hydroxypropyl groups;

That preparations including L-HPC, as illustrated by Comparative Examples 3, 4 and 5 were far less effective than the preparations of the invention of the '453 patent which did not include any L-HPC, as evidenced by the buccal dissolution time as reported in Tables 2, 4 and 6;

That from the teaching of the '453 reference, there would have been no reasonable expectation of success in the use of L-HPC having 5% by weight or more to less than 7% by weight of hydroxypropyl groups.

It is declared by the undersigned that all statements made herein of his knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 24<sup>th</sup> day of November, 2001

Yasuo Ohno  
Yasuo Ohno